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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,533	11/21/2001	George M. Grass	109904-00067	1149

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EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,533

Applicant(s)

GRASS ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/21/01</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election of the species of GI tract in the reply filed on 4/2/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

An action on the merits of claims 1-20, as they read on the elected species, follows.

Information Disclosure Statement

The information disclosure statement filed 11/21/01 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because some of the citations therein lack dates and/or source of publication. The IDS has been placed in the application file, but all the information referred to therein has **not** been considered as to the merits. References DS, DT on page 6, DK on page 7, DW on page 8, all of which lack dates. References ES, EU, EW, and FH on pages 9-11 lack sources of publication. References ED and EM on pages 8-9 are duplicative of citations listed elsewhere in the IDS, and have been crossed out to avoid duplication on printing of an associated patent or publication. The examiner's signature indicates that only the initialed references have been considered.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with

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the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 17 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

Secondary libraries of compounds are not described. Both the pending claims and instant specification, on pages 23-27, disclose a method of creating a secondary compound library by using in silico steps of screening (presumably for) various absorption, permeability, and/or solubility characteristics, but neither the claims nor the specification describe the library so created, nor any individual members of the library, such that one of skill in the art would have recognized that the inventors indeed has possession of a secondary library. Neither the library, nor individual members thereof, are identified by structure, other physical characteristics, specific properties, or other characteristics such that one skilled in the art would know what sorts of compounds are

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comprised within the library. The specification discloses that the instant method (e.g. of claim 10) may be used to find compounds which are similar in activity or properties (e.g. absorption), but not necessarily in structure, but fails to describe any library produced by the method. The specification does not describe any secondary library with structural or functional limitations such that one of skill in the art would be able to envision the library, or any individual members thereof. As no secondary library is described anywhere, the claims are rejected for lack of written description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, in step (i), recites a phrase in square brackets. As it is unclear whether the limitation in the brackets are intended to be positive limitations of the claims, the use of the brackets renders the claim indefinite. This rejection may be overcome by removing the brackets, deleting the entire phrase, including the brackets, or other amendment which renders the intended limitation clear.

Claim 1 recites a final step of producing a secondary compound library having a desired absorption profile. As the first step of the claim appears to be an in silico one, it is unclear if the step of production is intended to be a physical step of a step of producing a virtual library, therefore the claim is indefinite. If a physical step, applicant

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is advised that the claim may not be enabled, as one of skill in the art would not necessarily know how to produce compound identified only by absorption characteristics. However, as it is unclear what limitation applicant intends, the claim is rejected herein only for indefiniteness.

Claims 1, 17 and 20 are directed to a library which is "produced" from the results of screening a primary library. The secondary library is identified only as one having a desired absorption profile, but is not otherwise described, as set forth above. The claim does not recite any definite structural or functional limitations of the secondary library such that one of skill in the art would be able to envision the library, or any individual members thereof. As one skilled in the art would not know the metes and bounds intended by applicant for the secondary library produced, the claim is indefinite.

Claims 2-8 recite apparent limitations of the product (library) of claim 1; however, the limitations actually appear to limit the steps of screening which "produce" the library. As it is unclear what structural or functional limitations of the claimed *library* are intended, claims 2-8 are indefinite.

Claims 8 and 9 recite method steps, but depend from claim 1, directed to a product. It is noted that claim 9 specifically recites "The method..." As it is unclear what limitation, if any, of the library of claim 1, is intended by the method steps of claims 8 and 9, the claims are indefinite.

Claim 10 limits a plurality of test samples to "contain isolated compounds or isolated mixtures of compounds per test sample". This phrase is awkward and confusing as it is unclear what each test sample is intended to comprise. If applicant

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intends that each test sample comprise an isolated compound or a mixture of isolated compounds (or an isolated mixture (?) Of compounds), then the claim should be rewritten to clearly reflect the intended limitation.

Step (i) of claim 10 appears to comprise a number of steps, written in a combination of passive and active voice. It is unclear if applicant intends the method claim to actually comprise the "passive" steps, or intends to limit the library, or test samples, or compounds, to be those generated by a particular method. If the latter, then it is further unclear what structural or functional limitations of the library are intended by the "generation" steps recited. If the former, then all intended steps should be rewritten using active, positive verbs.

Step (ii) of claim 10 recites a step of producing a compound library, whereby the library or a portion thereof "are screened by absorption." It is unclear if applicant intends to perform a screening step AFTER production of the library, or intends to produce a library which has been selected (or previously screened) for particular absorption characteristics; i.e. production of a library wherein the members of the library are identified by particular absorption profiles, etc. It is noted that the examiner is not suggesting claim language, but merely exemplifying various interpretations of the claim language. As it is unclear what steps are intended by applicant in both parts (i) and (ii) of the claim, claim 10 is indefinite.

Claim 10 is directed to a method of screening a compound library by absorption and recites a step (i) of screening. The term "screening" implies that one is screening FOR or AGAINST certain properties or characteristics; however, the claims do not recite

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anywhere what is to be screened “for” or “against”. Similarly, claim 18 recites screening a library “by other properties” and “selecting by one or more” of the properties, but fails to recite what is to be selected (e.g. compounds which comprise the properties? compounds which do NOT comprise the properties? compounds which comprise a property above (or below) a particular level? Comprise which comprise a selected combination of properties? etc.) As one skilled in the art would not know to what to include or exclude in screening and/or selecting a library “by absorption” or “by other properties”, the claims are indefinite.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-9, 17, and 20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over AMIDON et al. (Pharm. Res. (1995) vol. 12, no. 3, pp. 413-420).

AMIDON teaches a set (library) and classes of compounds with identified solubility and permeability, or absorption profiles (see Tables I and II), thus anticipating claims 1-9, 17 and 20. See MPEP 2113.

Claims 1-9, 17, and 20 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over DOWTY et al. (Pharm. Res. (12/1997) vol. 14, no. 12, pp. 1792-1797).

DOWTY teaches a set (library) of compounds selected from rat and human drug experimental data sets wherein the library is selected and identified by absorption characteristics (Table I), thereby anticipating claims 1-9, 17, and 20. See MPEP 2113.

Claims 1-9, 17, and 20 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over FECIK et al. (Med. Res. Rev. (5/1998) vol. 18, no. 3, pp. 149-185).

FECIK teaches a secondary library of compounds selected from a primary library of marketed drugs wherein the drugs are screened for bioavailability and absorption (see Appendix: A), thereby anticipating claims 1-9, 17, and 20. See MPEP 2113.

Conclusion

Claims 1-20 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
7/24/04